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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,355	03/01/2002	Richard C. Boucher JR.	5470.250DV	3423

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PO BOX 37428
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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,355

Applicant(s)

BOUCHER, RICHARD C.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 14-21,31-51 is/are pending in the application.
- 4a) Of the above claim(s) 16-19,21 and 45-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,14,15,20,31-44,50-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted February 20, 2003 is acknowledged.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1, 15, 31-36, 42-44 and 50-51 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Scheele (U.S. Patent 5,863,563) for reasons set forth in the prior office action.

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 14, 15, 20, 31-44 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (U.S. Patent 5,863,563) in view of Glass (U.S. Patent 5,162,348) for reasons set forth in the prior office action.

Response to the Arguments

Applicants' amendments and remarks submitted February 20, 2003 have been fully considered, but are not persuasive for reasons discussed below.

1. Applicants argue that claims 1, 15, 20, 31-36, 42-44, and 50-51 are not anticipated by Scheele because Scheele does not teach all the limitation claimed herein. Applicants' arguments focus on the mechanistic differences between the references and instant application, fails to specify any material deference between the two methods. As stated in the prior office action, Scheele teaches a method of treating patient with cystic fibrosis comprising causing the patient inhale a composition comprising potassium bicarbonate. The instant claims, read on treating cystic fibrosis patient with potassium bicarbonate. Note, particular property description of an old compound, such as "osmotically active," would not make the old compound distinct. The instant claims are directed to effecting a biochemical pathway with an old and well known method. The argument that such claims are not directed to the old and well known ultimate utility (treating cystic fibrosis patient) for the method, e.g., employing potassium carbonate for treating cystic fibrosis patient, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various physiological interpretations. The ultimate utility for the claimed method is old and well known rendering the claimed subject

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matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 102. Further, applicants fails to point out that the method of Scheele would have not led to the functional limitation herein, i.e., "to increase the volume of liquid on the airway surface." In fact, the dosage employed herein is in the same range of those disclosed in Scheele. See, page 10, lines 15-19, in instant application. And col. 12, lines 4-27 in Scheele.

2. Applicants further argue that Scheele fails to provide teachings that enable the instant invention. Particularly, one of ordinary skill would have not expected the method disclosed by Scheele would have increased the volume of liquid on the airway. First, as discussed above, the functional limitation of a old and well-known method does not render the old and well-known method patentable distinct; Second, one of ordinary skill in the art would have reasonably expected that the administration of inorganic salts, such as potassium bicarbonate, to the airway surface, would result in the liquid secretion on the surface, because such inorganic salts are well-known osmotically active agents.

3. Applicants argue that claims 1, 15, 20, 31-36, 42-44, and 50-51 are not obvious over Scheele and Glass because the references do not teach all the limitation claimed herein. Particularly, the cited references do not teach the particular function herein claimed. As discussed above, such functional limitations do not render an old and well-known method patentably distinct.

Applicants specifically argue that claim 37 is not obvious over the cited references because the cited references do not teach expressly the employment of the combination of salts sharing a common anion or cation. Such arguments are not probative. Particularly, each and every compound in the combination are known to be useful for the same purpose, (e.g.,

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potassium bicarbonate, and sodium bicarbonate), it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known germicides sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Further, Scheele teaches that mixture of potassium bicarbonate, and sodium bicarbonate is a preferred embodiment of the invention.

Nothing unobvious is seen for the claimed invention.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

~~SHENGJUN WANG~~
~~PATENT EXAMINER~~

Shengjun Wang

May 12, 2003